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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/748,739	12/26/2000	Oksana Lockridge	P-IX 4143	4261

23601 7590 09/27/2002

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EXAMINER
CELSA, BENNETT M

ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 09/27/2002 12

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary

Application No.	Applicant(s)
09/748,739	Lockridge et al.
Examiner	**Art Unit**
Bennett Celsa	1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-39* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-39 are currently pending.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2 (in part), drawn to peptide comprising substantially the same amino acid sequence as seq. Id 2, classified in class 530, subclass 324.

II. Claims 1-2(in part), drawn to a "functional" peptide "fragment" of seq. Id. 2, classified in class 530, various subclasses dependent upon the size of the fragment.

III. Claims 4-5 (in part), drawn to peptide comprising substantially the same amino acid sequence as seq. Id 4, classified in class 530, subclass 324.

IV. Claims 4-5 (in part), drawn to a "functional" peptide "fragment" of seq. Id. 4, classified in class 530, various subclasses dependent upon the size of the fragment.

V. Claims 7-8 (in part), drawn to peptide comprising substantially the same amino acid sequence as seq. Id 6, classified in class 530, subclass 324.

VI. Claims 7-8 (in part), drawn to a "functional" peptide "fragment" of seq. Id. 6, classified in class 530, various subclasses dependent upon the size of the fragment.

VII. Claims 10-11 (in part), drawn to peptide comprising substantially the same amino acid sequence as seq. Id 8, classified in class 530, subclass 324.

VIII. Claims 10-11(in part), drawn to a "functional" peptide "fragment" of seq. Id. 8, classified in class 530, various subclasses dependent upon the size of the fragment.

IX. Claim 3 (in part), drawn to a nucleic acid (N.A.) (e.g. encoding a "variant") comprising substantially the same nucleic acid as seq. Id. 1, classified in class 536, subclass 23.1

X. Claim 3 (in part), drawn to a nucleic acid "fragment" (e.g. probe or primer) of seq. Id. 1, classified in class 536, subclass 24.3.

XI. Claim 6 (in part), drawn to a nucleic acid (N.A.) (e.g. encoding a "variant") comprising substantially the same nucleic acid as seq. Id. 3, classified in class 536, subclass 23.1

XII. Claim 6 (in part), drawn to a nucleic acid "fragment" (e.g. probe or primer) of seq. Id. 3, classified in class 536, subclass 24.3.

XIII Claim 9 (in part), drawn to a nucleic acid (N.A.) (e.g. encoding a "variant") comprising substantially the same nucleic acid as seq. Id. 5, classified in class 536, subclass 23.1

XIV Claim 9 (in part), drawn to a nucleic acid "fragment" (e.g. probe or primer) of seq. Id. 5, classified in class 536, subclass 24.3.

XV. Claim 12 (in part), drawn to a nucleic acid (N.A.) (e.g. encoding a "variant") comprising substantially the same nucleic acid as seq. Id. 7, classified in class 536, subclass 23.1

XVI. Claim 12 (in part), drawn to a nucleic acid "fragment" (e.g. probe or primer) of seq. Id. 7, classified in class 536, subclass 24.3.

XVII. Claim 13 (in part),14 and 15 drawn to a library comprised of "variant" peptides comprising "at least one amino acid alteration of seq. 9, class 435, subclass digest 35.

XVIII. Claim 13 (in part), 14 and 15, drawn to a library comprising "functional fragments" of "variant" peptides comprising "at least one amino acid alteration of seq. 9, class 435, subclass digest 35.

XIX. Claim 13 (in part),14 and 16 drawn to a library comprising of "variant" peptides comprising "at least one amino acid alteration of seq. 10, class 435, subclass digest 35.

XX. Claim 13 (in part), 14 and 16, drawn to a library comprising "functional fragments" of "variant" peptides comprising "at least one amino acid alteration of seq.10, class 435, subclass digest 35.

XXI. Claim 13 (in part),14 and 17 drawn to a library comprising of "variant" peptides comprising "at least one amino acid alteration of seq. 11, class 435, subclass digest 35.

XXII. Claim 13 (in part), 14 and 17, drawn to a library comprising "functional fragments" of "variant" peptides comprising "at least one amino acid alteration of seq. 11, class 435, subclass digest 35.

XXIII. Claim 13 (in part),14 and 18 drawn to a library comprising of "variant" peptides comprising "at least one amino acid alteration of seq. 12, class 435, subclass digest 35.

XXIV Claim 13 (in part), 14 and 18, drawn to a library comprising "functional fragments" of "variant" peptides comprising "at least one amino acid alteration of seq.12, class 435, subclass digest 35.

XXV. Claim 13 (in part),14 and 19 drawn to a library comprising of "variant" peptides comprising "at least one amino acid alteration of seq. 13, class 435, subclass digest 35.

XXVI Claim 13 (in part), 14 and 19, drawn to a library comprising "functional fragments" of "variant" peptides comprising "at least one amino acid alteration of seq. 13, class 435, subclass digest 35.

XXVII. Claim 13 (in part),14 and 20 drawn to a library comprising of "variant" peptides comprising "at least one amino acid alteration of seq. 14, class 435, subclass digest 35.

XXVIII. Claim 13 (in part), 14 and 20, drawn to a library comprising "functional fragments" of "variant" peptides comprising "at least one amino acid alteration of seq.14, class 435, subclass digest 35.

XXIX. Claim 13 (in part),14 and 21 drawn to a library comprising of "variant" peptides comprising "at least one amino acid alteration of seq. 15, class 435, subclass digest 35.

XXX. Claim 13 (in part), 14 and 21, drawn to a library comprising "functional fragments" of "variant" peptides comprising "at least one amino acid alteration of seq.15, class 435, subclass digest 35.

XXXI. Claim 22 (in part) and 23 drawn to a library of nucleic acids encoding"variant" peptides comprising "at least one amino acid alteration of seq. 9, class 435, subclass digest , classified in class 435, subclass digest 37.

XXXII. Claim 22 (in part) and 23 drawn to a library of nucleic acids encoding "functional fragments" of "variant" peptides comprising "at least one amino acid alteration of seq. 9, class 435, subclass digest , classified in class 435, subclass digest 37.

XXXIII. Claim 22 (in part) and 24 drawn to a library of nucleic acids encoding"variant" peptides comprising "at least one amino acid alteration of seq.10, class 435, subclass digest 37.

XXXIV. Claim 22 (in part) and 24 drawn to a library of nucleic acids encoding "functional fragments" of "variant" peptides comprising "at least one amino acid alteration of seq. 10, class 435, subclass digest 37.

XXXV. Claim 22 (in part) and 25 drawn to a library of nucleic acids encoding"variant" peptides comprising "at least one amino acid alteration of seq.11, class 435, subclass digest 37.

XXXVI. Claim 22 (in part) and 25 drawn to a library of nucleic acids encoding "functional fragments" of "variant" peptides comprising "at least one amino acid alteration of seq. 11, class 435, subclass digest 37.

XXXVII. Claim 22 (in part) and 26 drawn to a library of nucleic acids encoding"variant" peptides comprising "at least one amino acid alteration of seq.12, class 435, subclass digest 37.

XXXVIII. Claim 22 (in part) and 26 drawn to a library of nucleic acids encoding "functional fragments" of "variant" peptides comprising "at least one amino acid alteration of seq. 12, class 435, subclass digest 37.

XXXIX Claim 22 (in part) and 27 drawn to a library of nucleic acids encoding"variant" peptides comprising "at least one amino acid alteration of seq.13, class 435, subclass digest 37.

XXXX. Claim 22 (in part) and 27 drawn to a library of nucleic acids encoding "functional fragments" of "variant" peptides comprising "at least one amino acid alteration of seq. 13, class 435, subclass digest 37.

XXXXI. Claim 22 (in part) and 28 drawn to a library of nucleic acids encoding"variant" peptides comprising at least one amino acid alteration of seq.14, class 435, subclass digest 37.

XXXXII. Claim 22 (in part) and 28 drawn to a library of nucleic acids encoding "functional fragments" of "variant" peptides comprising at least one amino acid alteration of seq. 14, class 435, subclass digest 37.

XXXXIII Claim 22 (in part) and 29 drawn to a library of nucleic acids encoding"variant" peptides comprising "at least one amino acid alteration of seq.15, class 435, subclass digest 37.

XXXXIV. Claim 22 (in part) and 29 drawn to a library of nucleic acids encoding "functional fragments" of "variant" peptides comprising "at least one amino acid alteration of seq. 15, class 435, subclass digest 37.

XXXXV. Claims 30-34 (in part), drawn to treating cocaine-induced conditions (e.g. hydrolyzing cocaine-based ... substrates) by administering (or contacting substrates) with a peptide of seq. Id. 2, classified in class 514, subclass 2.

XXXXVI. Claims 30-34 (in part), drawn to treating cocaine-induced conditions (e.g. hydrolyzing cocaine-based ... substrates) by administering (or contacting substrates) with a "functional fragment" of the peptide of seq. Id 2, classified in class 514 , subclass 3+ (dependent upon size of peptide).

XXXXVII. Claims 35-39 (in part), drawn to treating cocaine-induced conditions (e.g. hydrolyzing cocaine-based ... substrates) by administering (or contacting substrates) with a peptide of seq. Id. 4, classified in class 514, subclass 2.

XXXXVIII. Claims 35-39 (in part), drawn to treating cocaine-induced conditions (e.g. hydrolyzing cocaine-based ... substrates) by administering (or contacting substrates) with a "functional fragment" of the peptide of seq. Id 4, classified in class 514 , subclass 3+ (dependent upon size of peptide).

XXXXIX. Claims 35-39 (in part), drawn to treating cocaine-induced conditions (e.g. hydrolyzing cocaine-based ... substrates) by administering (or contacting substrates) with a peptide of seq. Id. 6, classified in class 514, subclass 2.

XXXXX. Claims 35-39 (in part), drawn to treating cocaine-induced conditions (e.g. hydrolyzing cocaine-based ... substrates) by administering (or contacting substrates) with a "functional fragment" of the peptide of seq. Id 6, classified in class 514 , subclass 3+ (dependent upon size of peptide).

XXXXXI. Claims 35-39 (in part), drawn to treating cocaine-induced conditions (e.g. hydrolyzing cocaine-based ... substrates) by administering (or contacting substrates) with a peptide of seq. Id. 8, classified in class 514, subclass 2.

XXXXXII. Claims 35-39 (in part), drawn to treating cocaine-induced conditions (e.g. hydrolyzing cocaine-based ... substrates) by administering (or contacting

substrates) with a "functional fragment" of the peptide of seq. Id 8, classified in class 514 , subclass 3+ (dependent upon size of peptide).

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I-VIII are independent and/or patentably distinct peptides due to differences in chemical structure and function, including different in amino acid content (seq, 2,4,6,8) and length (fragments thereof) which results in peptides with different primary and secondary amino acid structure, different physicochemical properties which are capable of separate manufacture and/or use; and which further require different and separately burdensome manual and computer sequence and bibliographic searches in patent and literature databases. Additionally, the fragments (e.g. different mers such as 6mers, 8mers ... >400 mers of a given seq. Id.) lack a common core structure necessary for a common utility.

4. Inventions IX-XVI are independent and/or patentably nucleic acid compounds due to differences in chemical structure and function, including different in nucleic acid content (seq, 1,3,5,7) and length (fragments thereof) which results in nucleic acids with different structure, different physicochemical properties which are capable of separate manufacture and/or use (e.g. encoding, probes, primers etc.) ; and which further require different and separately burdensome manual and computer sequence and bibliographic searches in patent and literature databases. Additionally, the fragments (e.g. different mers such as 6mers, 8mers ... >400 mers of a given seq. Id.) lack a common core structure necessary for a common utility.

5. The peptides of Inventions I-VIII are independent and/or patentably distinct peptides as compared to the nucleic acids of Inventions IX-XVI, due to differences in chemical structure and function, different physicochemical properties which are capable of separate manufacture and/or use; and which further require different and separately burdensome manual and computer sequence and bibliographic searches in patent and literature databases.

6. Inventions XVI-XXX are independent and/or patentably libraries since the individual libraries comprise different distinct peptides due to differences in chemical structure and function, including different in amino acid content (seq, 9-15) and length (fragments thereof) which results in libraries containing different peptides with different primary and secondary amino acid structure, different physicochemical properties which are capable of separate manufacture and/or use; and which further require different and separately burdensome manual and computer sequence and bibliographic searches in patent and literature databases. Additionally, the fragments (e.g. different mers such as 6mers, 8mers ... >400 mers of a given seq. Id.) lack a common core structure necessary for a common utility.

7. Inventions XXXI-XXXXIV are independent and/or patentably libraries of nucleic acid compounds due to differences in chemical structure and function, including different nucleic acid content and length (fragments thereof) which results in nucleic acids with different structure, different physicochemical properties which are capable of separate manufacture and/or use (e.g. encoding, probes, primers etc.) ; and which further require different and separately burdensome manual and computer sequence and bibliographic searches in patent and literature databases.

Additionally, the fragments (e.g. different mers such as 6mers, 8mers ... >400 mers of a given seq. Id.) lack a common core structure necessary for a common utility.

8. The libraries of peptides of Inventions XVI-XXX are independent and/or patentably distinct peptides as compared to the libraries of nucleic acids of Inventions XXXI-XXXXIV, due to differences between nucleic acids and peptides in chemical structure and function, different physicochemical properties which are capable of separate manufacture and/or use; and which further require different and separately burdensome manual and computer sequence and bibliographic searches in patent and literature databases

9. The methods of Inventions XXXXV-XXXXXII are independent and/or patentably distinct from each other due to the separate use of therapeutic agents (e.g. peptides) which are independent and/or patentably distinct from each other due to differences in chemical structure and function, including different in amino acid content (seq, 2,4,6,8) and length (fragments thereof) which results in peptides with different primary and secondary amino acid structure, different physicochemical properties which are capable of separate manufacture and/or use; and which further require different and separately burdensome manual and computer sequence and bibliographic searches in patent and literature databases. Additionally, the fragments (e.g. different mers such as 6mers, 8mers ... >400 mers of a given seq. Id.) lack a common core structure necessary for a common utility.

10. Inventions (I/II/III/IV/V/VI/VII/VIII) and (any one of XXXXV-XXXXXII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product as demonstrated by the alternative use of peptides and fragments of Inventions I-VIII which constitute independent and/or patentably distinct peptides (e.g. item 1. above providing reasons) or the use of other agents (e.g. dopamine antagonists) to treat cocaine addiction (e.g. see specification pages 1-3 et al.

11. Because these inventions are distinct for the reasons given above and

a. have acquired a separate status in the art as shown by their different classification; and/or

b. because the search required for the different inventions are different e.g. classification and/or bibliographic and/or sequence manual and computer searches in patent and literature databases; and/or

c. because these inventions have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Further Restriction/Election

12. This application contains claims directed to the following patentably distinct species of the claimed invention:

A. "Functional peptide **fragments"** (e.g. Groups II, IV, VI, VIII, XVIII, XX, XXII, XXIV, XXVI, XXVIII etc.) or the use thereof (e.g. Groups XXXXVI, XXXXVIII, XXXXX, XXXXXII etc.)

B. "Nucleic acid **fragments**" (e.g. Groups X, XII, XIV, XVI etc.).

The above-identified fragments (or the use of such fragments) encompass different sizes: e.g. 6mers , 8mers, 10mers, 15mers full length -1 peptide or nucleic acid. See specification pages 13-14. Accordingly, these peptide and nucleic acid fragments are individually independent and/or patentably distinct since they encompass potentially millions (or more) of different peptides and nucleotides of different sequence composition (e.g.amino acid or nucleic acid content) and size, which possess different chemical properties and which are capable of separate manufacture and/or use. Additionally, individually these peptide (or nucleic acid) fragments require separate and individually burdensome manual and computer sequence and bibliographic searches in both patent and literature databases. Further, the fragments lack any common core structure necessary to elicit a common activity; nor does the patent office possess the facilities to search millions (or more) of differently sized peptides or nucleic acids, rendering applicant's claimed invention unsearchable.

Accordingly, Applicant is required under 35 U.S.C. 121 to **elect a single disclosed mer species** (e.g. **a specific size of nucleic acid or peptide fragment: e.g. ONE OF a 3mer, 4mer ... up to the entire sequence -1**) for prosecution on the merits to which the claims shall be restricted.

Applicant is advised that a reply to this requirement must include an identification of a species (a single sized nucleic acid or peptide fragment) that is elected consonant with this requirement.

Should applicant traverse on the ground that the various (mer) species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang (art unit 1627), can be reached at (703)306-3217.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1627)

September 26, 2002

BENNETT CELSA
PRIMARY EXAMINER